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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/292,411 04/15/1999 DAVID J. PAYNE GM50005-D1 3526

25181 7590 04/22/2003

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/22/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/292,411

Applicant(s)
Payne et al

Examiner
Mark Navarro

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-30 is/are allowed.
- 6) ☒ Claim(s) 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1645

DETAILED ACTION

Applicant's amendment filed April 9, 2003, (Paper Number 14) has been received and entered. Claims 35-37 have been added, consequently claims 25-37 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 31-34 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a written description rejection.

Additionally, this rejection is applied to newly added claims 35-37.

Applicant's are asserting that page 21, lines 24-26 describe a variety of 20 amino acid regions of the Fab I protein, either as individual fragments or as contiguous combinations thereof. Applicant's further assert that page 21, lines 27-30 describes a variety of fragments that are highly homologous to other proteins, which would indicate a highly conserved region with an important enzymatic or structural function. Applicant's further assert that pages 22 and 23 contemplates fragments that comprise certain structural features, such as alpha helix forming regions, beta sheet regions, coil regions, hydrophobic regions, etc. Applicant's further assert that the polypeptide fragments retain a biological activity of Fab I.

Art Unit: 1645

Applicant's arguments have been fully considered but are not found to be fully persuasive.

As stated previously, Applicant's claims (30/50 consecutive amino acids of SEQ ID NO: 2) include numerous structural variants. Applicant's solely disclosed protein is that of SEQ ID NO: 2. Applicant's have not determined the activity of SEQ ID NO: 2, let alone any fragment of SEQ ID NO: 2. Consequently, the common attributes to identify the members of the genus is lacking. Applicant's assertions about homology to other proteins are noted. However, which protein and more specifically which activity is the fragment going to share similar properties with?

Applicant's have further attempted to amend the claim to recite that the fragment has at least one biological activity of Fab I. However, while this is a baby step in the right direction, which of the numerous potential biological activities are being evaluated. (e.g., trypticase, hydrolase, ATPase, enolase, stimulates IL-1 production, stimulates IL-2 production, etc.) Without a readily identifiable function, the members of the genus remain inadequately described.

Claims 31-37 recite a polypeptide comprising a fragment of SEQ ID NO: 2 comprising at least 30/50 consecutive amino acids.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or

Art Unit: 1645

characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 2 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by the 30 consecutive amino acids of SEQ ID NO: 2 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in Paper Number 12, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

2. The rejection of claims 31-34 under 35 U.S.C. 102(e) as being clearly anticipated by Bailey et al (U.S. Patent no 6,403,337, filed on February 14, 2000, issued June 11, 2002 with full

Art Unit: 1645

priority under 119(e) to provisional 60/009,861 filed January 5, 1996) is withdrawn in view of Applicant's amendment.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

3. Claims 31-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant's have amended the claims to recite that the isolated polypeptide comprises the amino acid at "position 191 of SEQ ID NO: 2." However, Applicant has failed to point to support for this particular site (amino acid 191). Applicant is required to demonstrate clear support (page and line number) or cancel the newly added limitations.

4. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

The claim is vague and indefinite in the recitation of under “stringent hybridization conditions.” The specification provides no definition of “stringent” nor of the physical or chemical conditions under which the hybridization will occur, further no degree of hybridization is set forth. Stringency, determined by physical and chemical conditions, establishes the degree of hybridization. Without providing the physical and chemical conditions under which hybridization is to take place, one of skill in the art would not be able to hybridize any nucleotide sequence with an intended DNA sequence due to the lack of physical and chemical conditions and the lack of clarity as to what constitutes an acceptable degree of hybridization versus what does not.

5. Claims 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “SEQ ID NO: 2, or its equivalent...” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what is the line of demarcation between an equivalent and a non-equivalent? Without a clear definition as to what is encompassed under the term “equivalent” one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Art Unit: 1645

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al.

The claims are directed to an isolated polypeptide comprising SEQ ID NO: 2, wherein said polypeptide comprises the amino acid at position 191 of SEQ ID NO: 2, or its equivalent, and said amino acid is glycine or a conservative substitution thereof.

Bailey et al (U.S. Patent Number 6,403,337) discloses a polypeptide of SEQ ID NO:6 from *Staphylococcus aureus*. Bailey et al teach of acceptable carriers for compositions and fusions with heterologous proteins (columns 102-111). Bailey et al teach that SEQ ID NO: 6 comprises amino acid residues 1-256 that are 99.5% identical over amino acid residues 1-256 of SEQ ID NO:1 as instantly claimed.

In view that the protein disclosed by Bailey et al comprises a glycine or a conservative substitution thereof in “an equivalent” of SEQ ID NO: 2, the disclosure of Bailey et al is deemed to anticipate the claimed invention.

Art Unit: 1645

Claims 25-30 are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

April 18, 2003